The inclusion of medical benefits, e.g. drugs, in the catalogue of services supplied (and paid for) by social health insurance systems is handled very differently in the European countries. Various instruments specify what kinds of benefits can be included and define various criteria for their reimbursement by the insurance funds, e.g. negative or positive lists, guidelines or levels of patients’ contributions. The systems and procedures used for decision making also differ with respect to processes, participation and transparency to outsiders, as seen for example in the cases of parliamentary decisions and the findings of expert committees. The German system of reimbursement within the statutory health insurance system has reached a turning point in its historical development. As a consequence of increasing cost pressure and of new requirements for the evaluation of new and innovative drugs, it is experiencing a new orientation. As a result of a few actual and surprising decisions regarding nonreimbursement of drugs by the statutory health insurance companies and also in connection with the most recent legislative developments, a fundamental discussion has broken out regarding the arrangements for reimbursement. This is all the more remarkable because reimbursement and nonreimbursement have far-reaching effects on the processes, structures and allocations in place throughout the entire statutory health insurance benefit system.

**Development of regulations relating to approval and reimbursement of drugs**

The comprehensive range of benefits supplied by the German statutory health insurance, the absence of direction, and the health insurance companies’ self-image as organizations that can cope with every illness and every impairment to their members’ health have prevented any systematic development of the statutory health insurance system’s catalogue of services in the past. This is why the question of reimbursement for medicines by the German statutory health insurance has hitherto been answered in practice with the approval for use or registration of these medicines. Following successful testing of a drug’s “quality” and “safety” and demonstration of its “clinical efficacy” and the issue of a certificate of suitability for marketing by the official body responsible for the approval of medicines, its eligibility for reimbursement was regarded as a given. As a result of the absence of modern law on medicines requiring documentation of their clinical efficacy before approval could be granted until the second half of the 1970s, products were paid for without any (adequate) demonstration of efficacy for a long time. Even today, over half the drugs available on the German market are not approved according to the law on medicines that has been in force since 1978. The discussion of drug reimbursement is therefore linked directly with the evaluation of various “old” substances with reference to the law on approval of medicines.

The part of the code of social law that governs statutory health insurance (SGB V, Sozialgesetzbuch, Buch fünf) derives the insurance policyholder’s entitlement to treatments with “therapeutic benefit”. Ultimately, this requirement can also be regarded as a condition for reimbursement for a drug by the statutory health insurance company. The distinction between a medicine’s efficacy and its “therapeutic benefit” remains the subject of vehement political and legal discussions even today. A (relevant) difference would provide a basis for a special test of eligibility for reimbursement by the statutory health insurance companies, which would open the way to new latitude in both evaluation and discretion. As a result, the latter view has led to detailed exclusion rules, which are reflected in the law or in guidelines. It is only since the end of the 1980s, that the institutions bearing the costs have regarded approval only as a necessary, and no longer as a sufficient criterion of
eligibility for reimbursement by the statutory health insurance company. This view has meanwhile also been accepted by the legislature, and in the last health reform act of 2000, regulations have been introduced that are aimed at achieving a separate test of eligibility for reimbursement in the future.

Even today, the German statutory health insurance system (GKV, Gesetzliche Krankenkassenversicherung) does not carry out any formal testing of medicines' eligibility for reimbursement by the insurance companies. Reimbursement in the case of an individual drug is much more likely to be achieved, because the exclusion criteria in place do not apply to the particular substance product group under scrutiny. It has to be admitted that unrelenting cost pressure on the statutory health insurance system and the increasing numbers of new active ingredients and of innovative drugs in past years have led to the practice, especially in the case of cost-intensive new developments, of giving binding instructions on their prescription. These can then have a strong influence on how and how often doctors prescribe the drug. Restrictive regulations governing the use of newly developed preparations on the one hand and uncritical acceptance of the way insurance companies have handled reimbursements for medications previously on the other have led to an increasing focus on this issue. Thus, the adjustment of the benefits system of the statutory health insurance system to match in with its “care duty” and the increasing numbers of new active ingredients and of innovative drugs in past years have led to the practice, especially in the case of cost-intensive new developments, of giving binding instructions on their prescription. These can then have a strong influence on how and how often doctors prescribe the drug. Restrictive regulations governing the use of newly developed preparations on the one hand and uncritical acceptance of the way insurance companies have handled reimbursements for medications previously on the other have led to an increasing focus on this issue. Thus, the adjustment of the benefits system of the statutory health insurance system to match in with its “care duty” and the practical definition of “therapeutic benefit” or even of “additional therapeutic benefit” of new medicines are items on the political agenda.

**Stipulations of the social code on eligibility of drugs for reimbursement**

International comparison suggests that the German statutory health insurance’s range of benefits is (unusually) comprehensive. Persons insured with statutory health insurances in Germany are entitled to preparations for diagnosis, treatment and – with some restrictions – prevention, e.g. vaccinations or secondary prophylaxis, of illnesses. Medicines can be prescribed by the admitted doctors and charged to the statutory health insurance companies:

- when they are necessary to correct a decline in health that would be expected to lead to illness in the foreseeable future
- to recognize and to cure illnesses, to prevent them from getting worse, or to relieve the symptoms of illness.

This rather broad formulation of the policyholders’ entitlement within the statutory health insurance is restricted or defined along two lines. It can be restricted directly by the legislature, e.g. by an exclusion embodied in a law or in a legal ordinance, issued by the Federal Ministry of Health. Exclusions from eligibility for reimbursement or restrictions on such eligibility can also be indirectly derived from the so-called obligation to the economic principle imposed by social code, part V. Like all services and treatments supplied within the statutory health insurance system, prescriptions for medicines are governed by the social law’s “principle of economy”. According to this, supplies and services must be sufficient, appropriate and economic; they must not exceed what is necessary. In addition, they must conform to the “generally recognized status of medical knowledge”. The legislature has delegated the specific task of applying the economic principle within ambulatory care to the federal committee of doctors and statutory health insurances (BÄK, Bundesausschuss der Ärzte und Krankenkassen), an organization with equal representation of the doctors accredited for the system and the statutory health insurances.

**Legally specified exclusions from eligibility for reimbursement**

Since the beginning of the 1980s various legal regulations have been brought in isolation that underpin exclusion criteria for medicines that are today part of legal practice. They are either listed directly in the social code as stipulations or have provided the legal basis for corresponding ordinances with the force of laws to be passed. Many detailed regulations have grown up over the course of time, and little systematic organization can be discerned when they are considered together. They have often been supported for political reasons, for example with citation of lacking or inadequate demonstration of efficacy during the development of the law on approval of medicines and the debate on eligibility for reimbursement described above, with arguments on family policies, or with thoughts about the balance between higher co-payment of insured persons for prescriptions and their complete exclusion from the list of drugs eligible for reimbursement by the statutory health insurances.

The current law on health insurance specifies, for example, that only medicines that are distributed by pharmacists can be regarded as eligible for reimbursement by the statutory health insurance companies. For adult insurance holders (over 18 years of age) the following drugs have been excluded from reimbursement by statutory health insurances:

- medicines indicated for colds and influenza infections,
- preparations for treatment of the mouth and throat,
- laxatives,
- medicines designed to combat travel sickness.

Preparations for so-called primary prophylaxis, i.e. prevention of illnesses or injuries without the presence of particular risk factors, and hormonal contraceptives for prevention of pregnancies of women who have reached the age of 21 years are not benefits that the statutory health insurance companies have any duty to provide.

In addition to this, since 1990 so-called “uneconomic medicines” have been excluded from eligibility for reimbursement. The category “uneconomic” was not in fact based on economic criteria, but depended heavily on demonstrations of clinical efficacy and availability of clinical data. A medicine is considered uneconomic in legal terms, if:

- it contains components that are not necessary for the declared aim of therapy
- the effect of the components cannot be assessed with adequate certainty because of the large number of active substances contained in the medicine
- the therapeutic benefit of the components, severally and/or together, has not been demonstrated.

Publication of the active ingredients and combinations of active ingredients of...